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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/234,208	01/20/1999	JONI KRISTIN DOHERTY	49321-1	6406

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EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/234,208

Applicant(s)

DOHERTY ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,8-10,18-20 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3,8-10,27 and 28 is/are allowed.
- 6) ☒ Claim(s) 18 is/are rejected.
- 7) ☒ Claim(s) 19, 20, 29, 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The amendment filed June 6, 2003, 2003 is acknowledged. Claims 29 and 30 were added.

Claims 1-3, 8-10, 18-20, and 27-30 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

3. The objection to claims 27 and 28 because they appear to be of exactly the same scope as claims 3 and 10 is withdrawn in view of the amendment.

Rejections Maintained:

4. The rejection of claim 18 under 35 U.S.C. 102(e) as being anticipated by Hudziak (U.S. Patent 6,399,063; issued June 4, 2002; effective filing date Jan. 25, 1988) is maintained for the reasons of record.

Claim 18 recites pharmaceutical compositions that comprise an agent that is a monoclonal antibody that binds to the extracellular domain of Her-2 in combination with at least a second agent. Hudziak discloses pharmaceutical compositions comprising an antibody to Her-2 and a second agent, such as a cytokine (TNF-alpha, TNF-beta, IL-2, IL-2, Interferon-gamma;

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see col. 7, lines 3 – 61; claims 8-13). Thus, Hudziak discloses the claimed pharmaceutical compositions.

Applicant's arguments have been carefully considered, but are unpersuasive. Applicant appears to be arguing that the claims read on monoclonal antibody combinations with second agents, where the second agent may only be one of items "a" or "b", as recited in the claim. However, such an interpretation is too narrow. As claim 18 currently reads, it is drawn to a pharmaceutical agent that is either "a", "b", or "c + any second agent", because of the proviso that the agent may not be "the monoclonal antibody alone". Item "c" is "a monoclonal antibody that binds to the extracellular domain of Her-2". The proviso language does not limit the second agent to either the agent of "a" or "b". Therefore, Hudziak disclosure reads on the claimed pharmaceutical agents, because Hudziak teaches pharmaceutical compositions that are combination of an antibody that binds to the extracellular domain of Her-2 in combination with a second agent.

Conclusion

Claims 1-3, 8-10, 27 and 28 are allowed. Claims 19, 20, 29 and 30 are objected to. Claim 18 is rejected. Claims 19, 20, 29, and 30 would be allowable if rewritten as independent claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
October 6, 2003


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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